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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/02/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

868,606

Applicant(s)

ISLAM et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 11/28/01

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 13-38 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

☒ Claim(s) 13-38 is/are rejected.

Claim(s) _____ is/are objected to.

Claim(s) _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

Notice of Informal Patent Application, PTO-152

Notice of Draftsperson's Patent Drawing Review, PTO-948

Other _____

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Amendment of 11/28/01 has been entered. Claims 13-38 are pending and under examination.

Claims 13-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

In claims 13, 17, 22-23, 28 and 33-34 "about 0.1mM" is new matter. The examiner finds no recitation of "0.1mM" in conjunction with "about" in the original disclosure.

Likewise, with respect to claims 22-23 and 33-34, the examiner finds no recitations of "0.025mM" or of "0.05mM" in combination with "about" in the original disclosure.

Applicant has therefore broadened the scope of his claims beyond the extent supported by the original disclosure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-21, 25-32 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Etcheverry et al. (U.S. 5,705,364 or WO 96/39488).

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The U.S. and WO documents are equivalent. The examiner will refer to the U.S. document by col. And line number.

Etcheverry et al. teach production of glycoproteins in a cell culturing production medium containing a 0.1 mM to 20mM concentration of alknoic acid/salt, such as sodium butyrate (e.g. col. 11, lines 53-67).

Since applicant's claims recite "less than about 0.1mM", applicant's claims clearly encompass the 0.1mM concentration taught by Etcheverry et al. Note also that, even if applicant did not recite "about", there would be an overlap of what applicant is claiming ad what Etcheverry et al. claim, since they recite "about 0.1mM" (col. 24, line 46). Claims 13 and 23 are thus anticipated.

Regarding claims 14 and 29 note col. 11, line 5+.

With respect to claims 15 and 30 see col. 14, lines 40+ .

Concerning claims 16 and 31 note col. 20, line 41.

Regarding claim 17, the "semi-continuous fed batch culture" method of Etcheverry et al. (col. 10, lines 57+) is considered consistent with "subculturing".

The butyric acid/sodium butyrate of Etcheverry et al. is consistent with claims 18-21 and 32.

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Regarding claims 25 and 36, see teachings of CHO cells at col. 10, lines 21+.

With respect to claims 26-27 and 37-38, note glycoproteins taught at col. 5, line 39 - col. 6, line 29.

Claims 13-14, 16, 18-21, 25-29, 31-32 and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischer et al. (WO 89/06636).

Fischer et al. teach production of proteins secreted by cultured cells in a medium containing "about 0.1 to 10.0 mM" (page 9, line 37) of butyric acid/salt thereof. Since applicant's upper limit overlaps Fischer et al.'s. lower limit claims 13 and 23 are anticipated, following the rationale applied supra to Etcheverry et al.

Regarding claims 14 and 29, note teachings of a growth phase for the cultured cells at page 10, lines 1+; page 13, lines 7-14; page 16, lines 3-10; page 17, lines 30+; page 23, lines 4-6.

With respect to claims 16 and 31, the time periods disclosed at page 14, lines 32-35 add up to more than 10 days.

Regarding claims 18-21 and 32, the teachings of sodium butyrate are consistent with these claims.

Regarding the CHO cell line of claims 25 and 36, note page 23, lines 8-9.

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With respect to claims 26-27 and 37-38, see various proteins taught at page 12, line 8; page 15, line 1; page 17, line 1.

Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Feld (EP 0,239,292).

Feld teaches production of proteins by cells cultured in the presence of an alkanic acid/salt thereof. The concentration thereof is between 0.1 mM and 200 mM (page 7, lines 3-5). As with the references cited supra, the overlap of applicants upper range limit and Feld's lower range limit anticipates claims 13 and 28.

With respect to instant claims 14 and 29 note page 9, lines 23+.

Regarding claims 15 and 30, see page 8, lines 26+.

Concerning claims 18-21 and 32, see page 7, lines 30-33.

Regarding claims 26-27 and 37-38 note proteins taught at page 6, lines 9-20.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Etcheverry et al.

In the event that applicant does not concur with the further above stated rejection of claim 17 under anticipation, this claim is taken as obvious. Subculturing of cells is art conventional (col. 20, lines 1-5 teaching subculturing during the production phase would have been arrived at by routine experimentation, and would have depended on numerous particular factors such as 1) the particular cell line used, 2) the volume of the production batches used, 3) the amount of protein needed, and numerous other particulars.

Claims 22-24 and 33-35 contain limitation allowable over prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the

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organization where this application or proceeding is assigned is
(703) 308-4242.

Any inquiry of a general nature or relating to the status of
this application or proceeding should be directed to the
receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

June 17, 2003

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644